

### **REMARKS**

Claims 7-31, 33-34, 43-46, and 48-49 are pending in this application, with claims 27-31, 33-34, 43-46 and 48-49 being under consideration. In this Amendment, claims 27 and 43 have been amended. Support for these amendments may be found, for example, at paragraph [0034] of the published version of Applicants' specification, which indicates that "[b]y outside surface is meant the portion of the glove that comes into contact with other objects such as patients, medical instruments, table tops, or counters."

Applicants submit that no new matter is presented herein.

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections in view of the amendments set forth above, and the remarks presented below.

#### ***The Presently-Claimed Invention***

The presently-claimed invention relates, generally, to a packaged antimicrobial elastomeric article that is essentially free of powder and/or starch, and is coated on an outside surface with at least one antimicrobial agent. The package comprises a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity. The antimicrobial activity of the elastomeric article is extended compared to an unpackaged elastomeric article. Further, the packaged elastomeric article is capable of being stored and/or transported for a period of time without significant loss of antimicrobial activity.

The claimed elastomeric articles beneficially minimize or reduce cross-contamination that can occur as a result of contact by a wearer or user of the article with more than one other object. When the antimicrobial agent is applied to the surface in contact with the wearer's hand, the elastomeric articles also inhibit growth of skin flora. See paragraph [0034]. The package system, which includes a moisture-resistant water-vapor impermeable barrier and a desiccant, reduces relative humidity and maintains

said reduced relative humidity in the vicinity of the antimicrobial elastomeric article. See paragraph [0037]-[0038].

**Rejection under 35 U.S.C. § 103(a)**

Claims 27-31, 33-34, 43-46, 48-49 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman").

Applicants respectfully traverse this rejection.

The Office Action relies upon Modak for allegedly disclosing an antimicrobial elastomeric article (a glove) that includes anti-infective agents such as chlorhexidine salts and quaternary ammonium halides, where the glove may be pretreated with an adsorption site saturating treatment including a quaternary ammonium compound such as didecyldimethylammonium chloride. Additionally, the Office Action asserts that Modak discloses gloves that are essentially free of starch and powder; however, it fails to provide any citation within Modak to support this interpretation. The Office Action takes the position that Modak discloses materials other than corn starch as lubricants, and further asserts that the Modak glove does not have any free powder because the inner coating including chlorhexidine gluconate and a lubricating agent also contains a polymer to create a uniform surface on the glove.

Applicants submit that these rebuttal points **support** the interpretation of Modak advanced in Applicants' previous response. Whether or not the powder in the Modak glove is corn starch or another powdered lubricant like zinc oxide or hydroxycellulose, and whether or not the powder is "free" (which Applicants assume is intended to mean that the powder is loose inside the glove) does not alter the fact that **Modak does not disclose an elastomeric article that is essentially free of powder and/or starch**, as that term is defined in Applicants' specification. Applicants presently-claimed invention relates to a packaged antimicrobial elastomeric article that is essentially free of powder and/or starch, which is exemplified in the specification as less than about 2 mg of

residue per glove, and preferably no or almost no powder or starch. It appears that the Office Action is intentionally misinterpreting the language of the claims and construing them so as to encompass articles that are not essentially free of powder and/or starch in order to maintain this rejection.

Applicants therefore respectfully submit that the Office Action's characterization of the disclosure of Modak is not correct, especially with respect to a disclosure regarding gloves that are essentially free of starch and/or powder. Further, in contrast to the Office Action's characterization, Modak relates to an antiviral surgical or examination glove including a biguanide anti-infective agent and a lubricating agent/donning aid which is preferably a modified corn starch. See col. 2, lines 20-22. Although a suitable lubricating agent may include other powders such as zinc oxide, hydroxycellulose, or corn starch that has been blocked with benzalkonium chloride, didecyltrimethylammonium chloride, or gluconic acid, Modak specifically teaches that it is preferably a modified corn starch. See col. 2, lines 20-22 and 51-63. The corn starch must be blocked in order to prevent the anti-infective agent from being adsorbed. The anti-infective agent is provided inside the glove to protect health care workers from exposure to pathogens, such as HIV and HBV. See col. 1, lines 32-40. This is different from the articles of the presently-claimed invention, which provide an antimicrobial outer coating in order to reduce cross-contamination.

Modak indicates that the coated gloves disclosed therein provide a "supplementary protective effect of the CHG coating when the latex barrier becomes permeable to infectious viral particles due to stretching, but appears 'physically intact.' In the study, the CHG coating was effective against the occasional passage of virus through compromised, semi-permeable gloves." See column 10, lines 59-63. In contrast, the focus of the present invention is on providing elastomeric articles that are "packaged by a process wherein the packaged glove is capable of being stored and/or transported for a period of time without significant loss of antimicrobial activity. The phrase 'without significant loss of antimicrobial activity' means that the packaged gloves

remain effective at killing at least one log<sub>10</sub> of the number of microbes which come into contact with the gloves." See paragraph [0039].

Modak discloses that "[a]fter the leaching step, the inner coating was formed by dipping the leached glove into a powder slurry containing 15% cornstarch, 0.2% Bardac 2250 and 2% chlorhexidine gluconate (CHG). To form this slurry 450 g of cornstarch was suspended in water and diluted to 2700 ml deionized water. 6 ml of Bardac 2250 was added to it and mixed well. This solution was mixed by placing on a magnetic stirrer and 300 ml of 20% CHG was added slowly and the mixing continued for 20 minutes. This slurry was then ready for use." See column 5, lines 9-18. Modak also indicates that in addition to absorption of the antiviral agent by the powder lubricant, "the antiviral agent may also be adsorbed or otherwise made unavailable for release by the elastomeric glove body. This is particularly significant in the case of natural rubber gloves which have a high affinity for chlorhexidine. This type of adsorption appears to be a major factor in loss of activity on storage. Specifically, it appears that chlorhexidine originally present in the inner coating may be taken up over time by the glove body to be released slowly, if at all, on contact with fluids." See column 3, lines 40-49. The only solutions to this problem identified by Modak involve a coating of an excess of antiviral agent, which is taken up into the glove to the point of saturation, or a coating of an absorption-preventing lubricating agent surfactant. See column 3, line 50 to column 4, line 26.

Applicants submit that those skilled in the art recognize the differences between antiviral coatings and antimicrobial coatings. In general, one key difference is the contact time required to kill. Modak discloses that "[t]he inner coating is effective to deliver an antivirally effective amount of the antiinfective agent within ten minutes of exposure to a liquid" (see Abstract) and "[t]he inner coating is formulated using nonadsorbent lubricating agents and sufficient antiinfective agent such that an effective antiviral amount of the antiinfective agent is released within ten minutes of being exposed to a fluid, e.g., blood, perspiration or other body fluid. Preferably the inner coating will provide substantially instantaneous release of the antiinfective agent so that

any virus present is killed in the minimum possible time." See column 3, lines 9-16. Applicants indicate in the specification that "[a] time period of one minute of contact is a preferred amount of time for measuring 'quick-kill' antimicrobial efficacy. One feature of the antimicrobial gloves according to the invention is to kill 90% of the initial number of microorganisms, i.e., 1 log<sub>10</sub> reduction, in one to five minutes." See paragraph [0031].

Applicants do not use powdered elastomeric articles to prevent the antimicrobial composition from being absorbed into the body of coated article, in part because the use of powder does not permit substantially instantaneous release, and also because a powder-based antimicrobial coating would not be suitable for an outer coating. As a result of using articles that are substantially free of powder or starch, Applicants have had to address a greater problem with absorption of the antimicrobial agent into the elastomer used to form the article. Applicants' invention relates to the discovery that "[t]he migration of antimicrobial agent away from the surface decreases the availability of the antimicrobial agent on the surface of the glove, thus reducing the quick-kill efficacy of the glove. The problem is particularly acute in gloves that are essentially free of powder or essentially free of starch." See paragraph [0039]. Applicants' solution to this problem, to provide the gloves in a package with a desiccant, is not disclosed or suggested by the cited references.

Applicants unexpectedly found that the activity of an antimicrobial agent provided on a glove surface was adversely impacted by moisture in the air, which prevented the antimicrobial agent from being released. In the specification, Applicants stated "the packaging structure protects antimicrobial-treated natural rubber gloves and nitrile rubber gloves from moisture attack and maintains significant antimicrobial activity after several days of aging. Without wishing to be bound by theory, it is believed that the gloves are protected from moisture that accelerates the migration of water-soluble CHG and BKC to the interior of the gloves by the packaging system, and as a result, can maintain antimicrobial efficacy even at relatively low concentrations (i.e., 0.75% in the case of natural rubber gloves) of CHG and BKC. Again, without wishing to be bound by theory, the differences between the results for natural rubber and nitrile rubber gloves

are attributed to differences in migration rates into the underlying substrate." See paragraph [0094].

The present inventor surprisingly found that the antimicrobial agent migrates into an elastomeric article due to the effect of moisture, i.e., that the mechanism of action is likely absorption, not adsorption. As a result of this discovery, the Applicants developed a package system which may include "an antimicrobial glove and packaging providing a water-vapor-impermeable barrier. Such a system may comprise a desiccant and/or an inert water-vapor free atmosphere such as nitrogen, helium, and/or argon." See paragraph [0037].

The secondary references do not remedy the deficiencies of Modak, nor do they identify the problem solved by the presently-claimed invention. Accordingly, Applicants submit that one skilled in the art would not look to McDevitt and/or Shichman to arrive at the presently-claimed invention.

McDevitt is cited for disclosing a finger glove that is contained in a package "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph [0189]. However, McDevitt does not remedy the deficiencies of Modak with respect to the presently-claimed invention. McDevitt relates to a finger glove formed from a nonwoven web material that is liquid impermeable, but vapor permeable. The finger glove may also include an elastic nonwoven material to provide form-fitting properties. The finger glove of McDevitt is intended for use as an applicator or personal cleaning product, such as a swab or oral hygiene device, but there is no disclosure of a packaged elastomeric article that is essentially free of powder and/or starch and is coated with at least one antimicrobial agent.

The Office Action characterizes Applicants' statements regarding the disclosure of McDevitt as an attack against an individual reference that cannot be used to show nonobviousness. However, Applicants submit that the prior remarks were not attacks on individual references, but rather were directed to pointing out the deficiencies in the references that necessarily lead to the conclusion that one skilled in the art would not

combine the references in the manner indicated in the Office Action in order to arrive at the presently-claimed invention.

Applicants submit that Modak does not disclose a packaged antimicrobial elastomeric article that is essentially free of powder and/or starch, and McDevitt also does not disclose a packaged antimicrobial elastomeric article that is essentially free of powder and/or starch. The fact that the two primary references do not disclose this feature of the presently-claimed invention is entitled to weight, especially in view of the fact that the Office Action concedes that the third reference, Shichman, is only cited for disclosing adding a dessicant to a package to reduce moisture and not for remedying the deficiencies of Modak and McDevitt. Further, Shichman merely discloses packages containing desiccants for preserving bioabsorbable articles, such as surgical staples and clips, and instruments that contain such articles. The articles do not incorporate antimicrobial agents, and there is no disclosure of preserving antimicrobial activity of an elastomeric article that is essentially free of powder and/or starch and is coated with at least one antimicrobial agent by including a desiccant in a package containing an antimicrobial elastomeric article. One skilled in the art would not be motivated to modify the teachings of Modak and McDevitt to arrive at the presently-claimed invention based on the disclosure of Shichman. Even if their teachings are combined, they still fail to disclose or suggest all of the features of the presently-claimed invention.

The Supreme Court has explained that "rejections [based] on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

The outstanding obviousness rejection fails to meet this requirement. Applicants therefore respectfully submit that the Office Action has not made a proper *prima facie* rejection under 35 U.S.C. § 103(a), because the combination of Modak, McDevitt, and Shichman fails to disclose or suggest a packaged antimicrobial elastomeric article that is essentially free of powder and/or starch, is coated with at least one antimicrobial agent, and is provided in a package comprising a desiccant for reducing relative

humidity in the vicinity of the elastomeric article, in order to extend the antimicrobial activity of the elastomeric article.

Nothing in the disclosures of Modak, McDevitt, and Shichman would lead one skilled in the art to modify them to arrive at the presently-claimed invention without the benefit of hindsight reconstruction based on Applicants' disclosure. Applicants therefore submit that claims 27-31, 33-34, 43-46 and 48-49 are not unpatentable over the combination of Modak, McDevitt, and Shichman, and respectfully request withdrawal of this rejection.



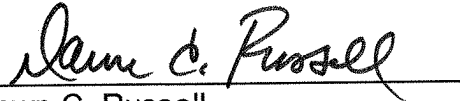
### CONCLUSION

In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of claims 27-31, 33-34, 43-46 and 48-49, and the prompt issuance of a Notice of Allowance are respectfully requested.

Should the Examiner believe that anything further is necessary in order to place this application in better condition for allowance, the Examiner is requested to contact the undersigned at the telephone number listed below.

In the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 01-2300 referencing docket number **029714.00017**.

Respectfully submitted,



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